

# Congress of the United States

Washington, DC 20515

March 22, 2001

The Honorable Donald Rumsfeld  
Secretary  
U.S. Department of Defense  
1000 Defense, The Pentagon  
Washington, D.C. 20301-1000

Dear Mr. Secretary:

As you continue with your efforts to complete a top-to-bottom review of our military, we are writing to strongly suggest a program that should be critically considered within this context - the Department's mandatory Anthrax Vaccination Immunization Program (AVIP). Over two years ago, your predecessor, Secretary Cohen, ordered the implementation of the force-wide anthrax vaccination program. Since that time, the AVIP has produced limited success, but great controversy.

On April 30, 1999, the Government Accounting Office (GAO) testified before the House Government Reform Committee that "the quality of a vaccine is closely linked to its manufacturing process, which must be rigorously controlled to ensure that batches of vaccines produced on different occasions are of reproducible and consistent quality...Accordingly, vaccine production is very highly regulated to ensure that the products are of consistent quality and safe and effective for the purpose(s) for which regulatory approval was granted." GAO further testified that the Food and Drug Administration had found deficiencies in its February 1998 inspection of the BioPort production facility that "fall broadly into two categories: those that, although serious, might affect only one or a limited number of batches that were produced when the deficiency was extant and those of a generic nature that could compromise the safety and efficacy of any or all batches." Right now, the anthrax vaccine being administered to U.S. military personnel around the world today was manufactured under those very conditions.

Unfortunately, that situation is little improved. Despite years of taxpayer investments exceeding over \$100 million, BioPort, the company contracted to produce the vaccine, still has not received an approved license supplement from the FDA. Their ongoing inspections continue to find serious deficiencies and deviations from good manufacturing practices. Further, the company, funded almost completely by the U.S. taxpayer, continues to be unable to demonstrate lot-to-lot antigen consistency for vaccines currently being produced for eventual approval. As a result, it would be extremely difficult to scientifically support a statement that each lot offers our troops the same level of protection as the next.

Beyond the problems of the company's approval, legitimate questions about the vaccine's safety persist. While the numbers of Vaccine Adverse Event Reports (VAERs) filed with FDA remain relatively small in number, this may be more a function of underreporting than a lack of adverse events. Late last year, GAO testified before Congress that 60 percent of the personnel participating in a survey of individuals who have taken the anthrax vaccine failed to report their adverse reactions. Of those personnel, 49 percent did not report their reactions for fear of losing flight status or concern over adverse effects on their military and civilian careers.

Even more troubling are recent press reports indicating that an October 2000 FDA inspection cited BioPort's initial failure to notify FDA of the possible anthrax-related death of Army Sergeant Nancy Rugo. The same report also indicated that BioPort had also failed to conduct an investigation into that death. These examples make it extremely difficult for Members of Congress and military personnel alike to have strong faith in the Department's reports of minimal adverse reactions.

Finally, perhaps one of the most disconcerting aspects of the AVIP program is the impact that it continues to have on the morale of our forces. Scores of otherwise outstanding military careers have been ruined because those individuals refused an order they thought would cause harm to them or their families. The GAO survey referenced earlier found that 25 percent of pilots and aircrew members interviewed were leaving the service because of the current anthrax vaccine program. Another 18 percent of those surveyed were planning to leave the service within 6 months and of those, 61 percent cited the AVIP program as the prime reason. The results from this small survey demonstrate the potentially devastating results on our ability to retain qualified military personnel if the protection program is restarted in its current form.

Mr. Secretary, we strongly support the need to protect our forces from the threat of biological attack. However, there must come a time when we realize that the current anthrax vaccine program is not going to succeed and that time is now. We urge you to impose an immediate temporary (4-6 months) moratorium on the mandatory vaccine program until the Administration is able to complete a thorough review in the context of your top to bottom discussions. We must stop investing precious resources in a failed initiative and instead redouble our efforts in the areas of detection capabilities, protection equipment, antibiotics, and recombinant vaccines addressing the multiple biological threats our forces face rather than just one. Rebuilding our military is not just a function of platforms and missions - it is about the men and women in uniform and the trust they must have in their military and civilian leadership. By making this decision, you will take an important steps towards ensure that this critical trust remains strong.

Thank you for your careful consideration of our request. We stand ready to assist you in addressing this important concern for all of our military personnel.

Sincerely,

Walter B. Jones

Jim Felman

Christopher Shays

Dan Burton

Bob Lee

George R. Rutherford

**Member Signatures, 3/22/01 Letter to Secretary Rumsfeld**

Walter B. Jones  
Ben Gilman  
Chris Shays  
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Curt Weldon  
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